

RALPH McELROY TRANSLATION COMPANY

EXCELLENCE WITH A SENSE OF URGENCY

September 5, 2001

Re: PCT Application No. PCT/EP 00/00876 with International Preliminary Examination Report with Amended Pages

To Whom It May Concern:

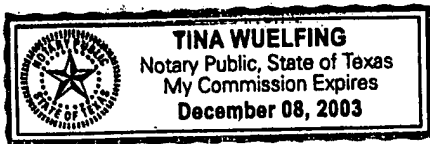
This is to certify that I am a professional translator who is skilled in the German language translated the enclosed PCT Application No. PCT/EP 00/00876 with International Preliminary Examination Report with Amended Pages from German into English.

I certify that the attached English translation conforms essentially to the original German language.

Mark A. Ritter

Mark Ritter
Translator

Subscribed and sworn to before me this 5 day of SEPTEMBER, 2001.



Tina Wuelfing
Tina Wuelfing
Notary Public

My commission expires: December 8, 2003

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PATENT COOPERATION TREATY

Sender: AGENCY TASKED WITH THE INTERNATIONAL
PRELIMINARY EXAMINATION

PCT

NOTIFICATION CONCERNING THE TRANSMISSION OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT (Rule 71.1 PCT)

To: WEICKMANN WEICKMANN HUBER LSKA PRECHTEL BÖHM WEISS TIESMEYER HERZOG RUTTENSBERGER JORDAN Kopernikusstrasse 9 D-81679 Munich GERMANY	[stamp:] RECEIVED May 16, 2001 Rec.:
File Number of the Applicant or Attorney 19503P WO	

Date Sent: (Day/Month/Year)	5/15/2001
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IMPORTANT NOTIFICATION

International Application Number PCT/EP00/00876 -	International Application Date (Day/Month/Year) 2/3/2000	Priority Date (Day/Month/Year) 2/3/1999
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Applicant
EUROPÄISCHES LABORATORIUM FÜR MOLEKULARBIOLOGIE et al.

1. The applicant is informed that the agency tasked with the international preliminary examination is transmitting herewith the international preliminary examination report developed for the international application with the relevant attachments if necessary.
2. A copy of the report, with the relevant attachments if necessary, is being transmitted to the International Bureau for further forwarding to all selected offices.
3. On request of a selected office, the International Bureau will prepare a translation of the report (but not the attachments) into English and transmit it to the office.
4. REMINDER

For entry into the national phase the applicant has to perform (Article 39 (1)) (see also the information transmitted in Form PCT/IB/301) certain transactions (filing of translations and payment of national fees) before each selected office within 30 months of the priority date (or still later in many offices).

If a translation of the international application is to be transmitted to a selected office, then this translation must also contain a translation of all attachments to the international preliminary examination report. It is the responsibility of the applicant to prepare such translations and transmit them directly to the relevant offices.

Further details concerning the authoritative deadlines and requirements of the selected offices are to be found in Volume II of the PCT guide for applicants.

Name and Address of the Agency Tasked with the International Examination [logo] Europäisches Patentamt D-80296 München Tel. +49 89 2399- 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Official Siedsma, Y. Tel. +49 89 2399
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PATENT COOPERATION TREATY
PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(Article 36 and Rule 70 PCT)

File Number of the Applicant or Attorney 19503 WO	ADDITIONAL PROCESSING see notification concerning the transmission of the international preliminary examination (Form PCT/IPEA/416)	
International Application Number PCT/EP00/00876	International Application Date (Day/Month/Year) 2/3/2000	Priority Date (Day/Month/Year) 2/3/1999
International Patent Classification (IPC) or national classification and IPC G01N33/543		
Applicant EUROPÄISCHES LABORATORIUM FÜR MOLEKULARBIOLOGIE et al..		
<p>1. This international preliminary examination report was developed by the agency tasked with the international preliminary examination and is being transmitted to the applicant pursuant to Article 36.</p> <p>2. This REPORT includes 5 pages in all including this cover sheet.</p> <p style="text-align: center;"><input checked="" type="checkbox"/> Furthermore, ATTACHMENTS accompany the report. They are pages with descriptions, claims, and/or drawings which were changed and are based on this report, and/or pages with corrections done before this agency (see Rule 70.16 and Section 607 of the Management Guidelines for the PCT).</p> <p style="text-align: center;">These attachments include 35 pages in all.</p>		
<p>3. This report contains specifications concerning the following points:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> No development of an opinion concerning novelty, inventive activity, and commercial applicability IV <input checked="" type="checkbox"/> Insufficient unity of the invention V <input checked="" type="checkbox"/> Substantiated finding according to Article 35(2) with regard to novelty, inventive activity, and commercial applicability; documents and explanations in support of this finding VI <input type="checkbox"/> Certain cited documents VII <input type="checkbox"/> Certain deficiencies in the international application VIII <input type="checkbox"/> Certain notes concerning the international application 		
Date of Filing of the Application 7/7/2000	Date of Completion of the Report 5/15/2001	
Name and Address of the Agency Tasked with the International Examination [logo] Europäisches Patentamt D-80296 München Tel. +49 89 2399 – 0 Tx: 523656 epmu d Fax: +49 89 2399 – 4465	Authorized Official Goetz, M. [logo] Tel. No. +49 89 2399 8697	

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International File No.: PCT/EP00/00876

I. Basis of the report

1. 1. With regard to the components of the international application (*Replacement pages that were submitted to the filing office in response to a request pursuant to Article 14 are considered "originally submitted" in the context of this report and are not appended to it, because they do not contain any amendments(Rules 70.16 and 70.17))*):

Specification, pages:

1-3, 3a-3b, 4-26 submitted on March 23, 2001 with letter of March 23, 2001

Claims, No.:

1-27 submitted on March 23, 2001 with letter of March 23, 2001

Drawings, sheets:

1/1 original version

2. With regard to the language: All the above-mentioned components were available to the authority in the language in which the international application had been submitted, or they were submitted in that language, unless information to the contrary is given under this point. The components were available to the authority in the language, or were submitted in this language, namely

the language of the translation, which was submitted for the purposes of the international search (pursuant to Rule 23.1 (b)).

The publication language of the international application (pursuant to Rule 48.3 (b)).

The language of the translation which was submitted for the purpose of the international preliminary examination (pursuant to Rule 55.2 and/or 55.3).

3. With regard to the nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence protocol which:

is contained in writing in the international application.

was submitted together with the international application in a computer readable form.

was subsequently submitted to the authority in written form.

EXAMINATION REPORT**INTERNATIONAL PRELIMINARY**
International File No.: PCT/EP00/00876

was subsequently submitted to the authority in a computer readable form.

The statement that the subsequently submitted written sequence protocol does not go beyond the disclosure content of the international application at the time of the application was submitted.

The statement that the information recorded in computer readable form corresponds to the written sequence protocol was submitted.

4. Because of the amendments, the following documents have been removed:

☐ Specification Pages:

☐ Claims No.:

☐ Drawings Sheets:

5. ☐ This report was prepared without taking account of (some of) the amendments since, in the view of the agency, these go beyond the disclosure in the originally submitted version, for the reasons stated (Rule 70.2(c)):

6. Any other remarks:

IV. Lack of unity of the invention

1. Upon the request to limit the claims or to pay additional fees, the applicant has:

limited the claims.

☒ paid additional fees.

paid additional fees with opposition.

neither limited the claims nor paid additional fees.

2. The authority has noted that the requirement of unity of the invention has not been fulfilled, and pursuant to Rule 68.1 it has decided not to request that the applicant limit the claims or pay additional fees.

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INTERNATIONAL PRELIMINARY
International File No.: PCT/EP00/00876

3. The authority is of the opinion that the requirement of unity of the invention according to Rules 13.1, 13.2 and 13.3

☒ has been met

has not been met for the following reason:

4. Therefore, for the preparation of this report, an international preliminary examination was carried out for the following parts of the international application:

☒ all parts.

the parts which pertain to Claims No.

V. Substantiated determination per Article 35(2) regarding novelty, inventive step and commercial applicability; documents and statements to support the determination

1. Determination

Novelty (N)	Yes: Claims 1-27 No: Claims
Inventive step(IS)	Yes: Claims 1-27 No: Claims
Commercial applicability (CA)	Yes: Claims 1-27 No: Claims

**2. Documents and statements
see appendix**

WORLD ORGANIZATION FOR INTELLECTUAL PROPERTY

International patent published on
the basis of the Patent Cooperation Treaty

INTERNATIONAL PUBLICATION NO. WO 00/46600 A2

International Patent Classification⁷: G 01 N 33/543

International Filing No.: PCT/EP00/00876

International Filing Date: February 3, 2000

International Publication Date: August 10, 2000

Priority

Date: February 3, 1999

Country: DE

No.: 199 04 288.8

Date: August 17, 1999

Country: DE

No.: 199 38 839.3

METHOD OF DETECTING ANALYTES IN A SAMPLE AND SUPPORT FOR THIS
PURPOSE

Inventor; and

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FOR INFORMATION ONLY

Codes for the identification of PCT contract states on the cover sheets of the documents that publish the international applications in accordance with the PCT.

AL	Albania	KE	Kenya	TG	Togo
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AU	Australia	KR	Republic of Korea	TR	Turkey
AZ	Azerbaijan	KZ	Kazakhstan	TT	Trinidad and Tobago
BA	Bosnia-Herzegovina	LC	Saint Lucia	UA	Ukraine
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BF	Burkina Faso	LR	Liberia	UZ	Uzbekistan
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IS	Iceland	TD	Chad		
IT	Italy				
JP	Japan				

International Preliminary Search Report—Added Sheet

International Application No. PCT/EP00/00876

On point V

Reasoned statement pursuant to Article 35(2) with regard to the novelty, the inventive activity and the susceptibility of industrial application; documents and explanations in support of this determination

1. Although documents D1-D4 describe differently designed supports in the CD disc format for the immunological analysis as well as methods for their preparation and their use, see

- D1, Figures 1-3, page 2/line 22 – page 3/line 2, page 6/line 18 – page 7/line 13, page 7/lines 17-23, page 10/line 16 – page 11/line 20, page 12/lines 7-13 and page 14/lines 5-18;
- D2, page 5/last paragraph – page 6/second paragraph, page 7/second and last paragraph/ page 8/last paragraph – page 9/first paragraph, page 15/second paragraph – page 16/second paragraph, page 17/last paragraph – page 21/first paragraph;
- D3, page 9/lines 15-37, page 10/lines 32-37, page 20/line 27 – page 26/line 16, page 32/lines 17-27, page 62/lines 31-34, Claims 18-26, 31 and 33;
- D4, Figure 1 and page 4/line 1 – page 5/line 7 and Claims 1-18,

the application of the reflector in the form of a reflecting layer, which is applied on the substrate (3) over the detection fields (5,7) (Claims 1 and 18) as well as the application of a planar magnetic layer (Claim 23) are not disclosed or obviously suggested according to the current state of knowledge by any of the cited oppositions.

2. Claims 1-27 therefore satisfy the prerequisites pursuant to Article 33(2)-(4) PCT.

Agent:

H. Weickmann et al.
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D-81679 Munich (DE)

Designated States:

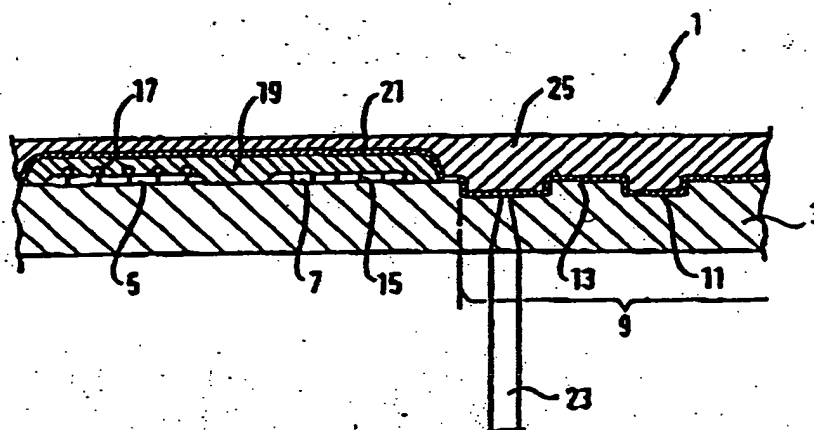
AU, CA, CN, JP, US, European
Patent (AT, BE, CH, CY, DE, DK,
ES, FI, FR, GB, GR, IE, IT, LU,
MC, NL, PT, SE).

Published

Without International Search Report and must be published again after reception of the report.

The invention relates to a method of detecting analytes in a sample. According to said method, analyte-specific binders (15) are immobilized on a plurality of detection fields (5, 7) on one of the planar faces of a disk-shaped substrate (3). The sample is contacted with said detection fields (5, 7) and the presence or/and the quantity of the analytes (17) to be detected is determined by optically evaluating the detection fields (5, 7). According to the invention, a substrate (3) is used that is produced from an optically transparent material. The detection fields (5, 7)

are arranged along at least one spiral line (27) distributed across the substrate (3). After the sample has been contacted with the detection fields (5, 7), a reflecting layer (21) is finally applied on the substrate (3) on the planar face carrying the detection fields (5, 7). Alternatively, a magnetic read-out of the substrate can be made instead of the optical read-out.



INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 00/00876

A. CLASSIFICATION F SUBJECT MATTER
IPC 7 601N33/551 611B7/013

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 601N 611B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ✓	WO 96 09548 A (GORDON JOHN FRANCIS ;UNIV DUNDEE (GB)) 28 March 1996 (1996-03-28) page 2, line 22 -page 3, line 2 page 6, line 18 -page 7, line 13 page 7, line 17-23 page 10, line 16 -page 11, line 20 page 12, line 7-13 page 14, line 5-18 page 8, line 15-19 figures 1-3	1,4-10, 12,17, 18,20, 31-33
Y	— —/—	26

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another claim or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"Z" document member of the same patent family

Date of the actual completion of the international search

10 October 2000

Date of mailing of the international search report

20.10.00

Name and mailing address of the ISA

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Authorized officer

Goetz, M

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/EP 00/00876

C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ✓	<p>WO 98 12559 A (DEMERS JAMES P) 26 March 1998 (1998-03-26)</p> <p>page 5, last paragraph -page 6, paragraph 2 page 7, paragraph 2 page 7, last paragraph page 8, last paragraph -page 9, paragraph 1 page 15, paragraph 2 -page 16, paragraph 2 page 17, last paragraph -page 21, paragraph 1</p>	<p>1,5-10, 17,18, 20,31-33</p>
Y		26
X ✓	<p>WO 98 01533 A (BURSTEIN LAB INC) 15 January 1998 (1998-01-15)</p> <p>page 9, line 15-37 page 10, line 32-37 page 20, line 27 -page 26, line 16 page 32, line 17-27 page 52, line 18 -page 54, line 7 page 62, line 31-34 claims 18-26,31,33</p>	<p>20, 26-29, 31-33</p>
Y ✓	<p>WO 96 05326 A (FOX JOHN S) 22 February 1996 (1996-02-22) page 4, line 1 -page 5, line 7 claims 1-18; figure 1</p>	26
A ✓	<p>T. SCHALKHAMMER: "Metal nano clusters as transducers for bioaffinity interactions" MONTASHEFTE FÜR CHEMIE/CHEMICAL MONTHLY, vol. 129, no. 10, 1998, pages 1067-1092, XP000917114 abstract</p>	1-25